DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 5,2014

Synthes (USA) Products LLC
Damon Lees
Senior Manager, Regulatory Affairs-CMF
1302 Wrights Lane East
West Chester, PA 19380

Re: K141165
Trade/Device Name: Matrix WAVE MMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 29, 2014
Received: September 2, 2014

Dear Mr. Lees:

This letter corrects our substantially equivalent letter of October 17, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K141165

Device Name:

MatrixWAVE MMF System

Indications for Use:

The MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary

Date Prepared: October 14, 2014

Submitter: Synthes (USA) Products LLC
1302 Wrights Lane East
West Chester, PA 19380
United States of America

Contact: Damon Lees
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(610) 719-5608
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Device Name: MatrixWAVE MMF System

Device Classification Information

Product Code	Device Name	Device Class	Regulation Number	Regulation Description
JEY	Plate, Bone	2	21 CFR 872.4760	Bone plate

In addition to the above type of implants, The MatrixWAVE MMF System also includes accessory items such as stainless steel wire and surgical instruments which are not the subject of this submission.

Predicate Device:

- Stryker Universal SMARTLock Hybrid MMF System (K122313)

Indications for Use:
The MatrixWAVE MMF System is indicated for the temporary treatment of mandibular and maxillary fractures and osteotomies in adults and adolescents (age 12 and higher) in whom permanent teeth have erupted.

Device Description:
MatrixWAVE MMF is a bone-borne maxillomandibular fixation (MMF) system that consists of wave shaped plates (made from commercially pure Titanium) that are attached to the dental arches with self-drilling locking screws (made from Titanium alloy, Ti-6Al-7Nb). The system is intended for temporary stabilization of mandibular and maxillary fractures and osteotomies to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (approximately 6-8 weeks). The dental arches are brought into occlusion by wiring around the plate hooks and/or accessible screw heads.

Comparison to Predicate Devices:

Indications
The MatrixWAVE MMF System has the same general Indications for Use as the predicate device.

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Technological Similarities of the MatrixWAVE MMF System to Predicate

- Same general principle of operation: metallic plates and screws each fixated to the mandible and maxilla, then wired together to achieve maxillomandibular fixation (MMF).
- Same or similar materials used for plates (Titanium), screws (Titanium alloy), and accessory wires (stainless steel).
- Compatible with similar diameter wires.
- Both use self-drilling screws with the same shaft (i.e. bone purchase) lengths.
- Both have a locking plate/screw interface.
- Both have plates that can be cut & contoured.
- Both have plates with pre-contoured hooks to support wires or elastics.
- Both are provided non-sterile.

Technological Differences of the MatrixWAVE MMF System to Predicate

- Screws in the proposed system have a smaller diameter.
- Screws in the proposed system have a raised head with a groove to accommodate wire(s) or elastics for additional (optional) stability.
- The plate/screw interface of the proposed system has pre-machined threads within the plate and can accommodate off-axis screw placement.
- The plates of the proposed system have a different shape, hole geometry, and dimensions.
- The plates of the proposed system can be compressed/expanded to accommodate patient anatomy and/or the location of screw holes.

Non-Clinical Performance Data:
Non-clinical testing and analyses comparing the proposed devices to the predicate within this submission includes: Mechanical Construct Testing, Screw Testing, Corrosion Testing, Hook Testing, and Biocompatibility Testing according to ISO 10993-18:2005. The non-clinical performance data demonstrate that the mechanical performance of the proposed MatrixWAVE MMF System is comparable to that of the predicate.

Clinical Performance Data:
Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence:
The proposed system has the same general indications as the predicate system. The mechanical testing included in this submission demonstrates that:

- Any differences in technological characteristics of the predicate do not raise any new questions of safety and effectiveness.
- The proposed devices are at least as safe and effective as the predicate.

It is concluded that the information included in this submission supports substantial equivalence.

(end of summary)